

Message

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Sent: 6/23/2021 11:25:33 AM
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Subject: More development on Ethylene Oxide - EPA Agrees to Reconsider Chemical Sector Air Rule Over Ethylene Oxide Assessment
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Leif,

Here are some of the highlights from “Inside EPA. com” article titled “*EPA Agrees to Reconsider Chemical Sector Air Rule Over Ethylene Oxide Assessment*,” published on 6/22/21

- EPA has agreed to requests from states, industry and environmental groups to reconsider the former administration’s controversial 2020 revision to its air toxics rule for the miscellaneous organic chemical manufacturing (MON) sector. This will open the door to strengthening the rule due to the risks posed by the solvent ethylene oxide (EtO).
- In a June 17th letter to the American Chemistry Council, EPA said it was granting reconsideration in light of an alternative EtO assessment conducted by the Texas Commission on Environmental Quality (TCEQ) that was completed after the comment period on the MON rulemaking closed.
- EPA’s acting air chief Joe Goffman also says the agency believes stricter rules are needed, a step that would address a host of concerns about the risks posed by EtO and calls by the agency’s Inspector General to better address those risks.

“Reconsideration is being granted on this topic on the basis that the TCEQ risk value for EtO was finalized after the comment period closed and because the risk posed by EtO is of central relevance to EPA’s determination that risks from sources in the MON source category are unacceptable and that more stringent standards are required,” Goffman writes.

- At the heart of the dispute is EPA’s Integrated Risk Information System (IRIS) assessment, which in 2016 found EtO to be many times more likely to cause cancer than previously believed. It recommended a limit of 0.1 parts per trillion (ppt) for a 1-in-a-million cancer risk.

- The IRIS assessment was the basis for EPA's last national air toxics assessment (NATA) that revealed elevated cancer risks in communities near facilities, such as medical equipment sterilizers, driving strong local opposition to these plants' operations. Some facilities have closed, while others will be subject to closer monitoring requirements and potentially tougher regulation in the future, with prominent members of Congress supporting efforts to reduce EtO risks.
- In addition, EPA's OIG, backed by environmentalists is also calling for EPA to conduct fresh risk-and-technology reviews (RTRs) of air toxics rules that regulate EtO, using the IRIS value.
- The MON rule was EPA's first regulation to use the conservative IRIS cancer risk value. But its use sparked significant concerns from industry officials, who charged that it overstates the chemical's cancer risk, by inappropriately using epidemiology studies of workers and choosing an extremely stringent modeling approach to determine the cancer risk estimate.
- To address the industry concerns, the agency increased the acceptable risks the rule would address, based in part on a draft version of TCEQ's risk analysis. While the agency noted that it generally uses a presumptive limit on maximum individual lifetime cancer risk of about 1-in-10 thousand or 100-in-1 million, in this case, it was willing to accept risks of 200- to 300-in-1-million due in part to "risk estimation uncertainty." EPA acknowledges that "[a]lthough the post-control risks are greater than 100-in-1 million (i.e., 200 to 300-in-1 million), due to the inherent health protective nature of our risk assessment methods and the uncertainties in this assessment, we believe that this risk assessment is more likely to overestimate rather than underestimate the risks."
- But environmental groups charged that any effort by EPA to step away from using the IRIS values is unlawful because the CAA requires use of "best available science." They also charged that TCEQ's draft analysis underestimates EtO's cancer risk by three orders of magnitude, excludes analyses on breast cancer studies and early life exposures, and was still in draft form.

- In consolidated litigation over the rule, environmentalists have also charged that EPA unlawfully opted against stricter emissions limits, failed to require fence-line air monitoring, and established illegal exemptions from the regulation.

EPA's reconsideration would appear to exclude most of environmentalists' issues, although the agency will treat its use of the IRIS value and its treatment of the TCEQ alternative as two distinct questions to reconsider, Goffman says. This might open the door to consideration of environmentalists' complaints that EPA in the MON rule relaxed the level of maximum individual lifetime cancer risk it would normally consider acceptable in such rules.

Also, EPA may decide to reconsider other issues raised in the petitions. Goffman writes, "We are continuing to review all issues raised in the petitions for reconsideration and may choose to initiate reconsideration of additional issues in the future."

But how EPA addresses such concerns is unclear.

See below, the link to the article:

<https://insideepa.com/daily-news/epa-agrees-reconsider-chemical-sector-air-rule-over-eto-assessment>



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